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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,639	08/25/2003	Patrick Camilleri	P31932D1	2524

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,639	CAMILLERI ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to preliminary amendment, claims 1-28, 30, 31 have been cancelled, and claims 29 and 32 amended. Claims 29 and 32 are pending.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have shown that representative compounds of the invention can promote transfection of a plasmid (encoding luciferase) into HEK 293 cells and into CHO-K1 cells. From this, applicants are asserting that they will be able to achieve an effective "gene therapy". The term at issue encompasses treatment of any disease. In reality, applicants have not demonstrated success in the treatment of even one disease.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or

absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. As it happens, one cannot "predict" success in the treatment of human disease merely because one is able to achieve transfection of a given gene. Consider, e.g., the following:

- Sawamura D (*Journal of Dermatological Science* 23 (2) 111-6, 2000) discloses that successful keratinocyte gene therapy requires development of effective methods for introducing genes into keratinocytes, and that previously used methods for in vivo gene transfer were not effective to maintain transgene in keratinocytes, and were not effective to achieve persistent expression of transgene.

- O'Malley B. W. (*Laryngoscope* 109 (3) 389-95, 1999) discloses that adenoviral interleukin-2 gene therapy has previously not been effective in treating established murine oral cancer.

- Madhusudan (*Clinical Cancer Research* 10, 2986-96, 2004) discloses that in attempting to achieve gene therapy involving the HER-2/*neu* oncogene, there was no correlation between dose and biological activity.

- Farquhar, David (*Cancer chemotherapy and pharmacology* 50 (1) 65-70, 2002) discloses an example of a gene therapy that was effective against tumor cells *in vitro*, but was not effective *in vivo*.

- Sturtz, F G (*Human gene therapy* **8** (16) 1945-53, 1997) discloses that attempts to use gene therapy in humans has not been effective, at least in therapies involving the thymidine kinase gene.

- Shaw, L C (*Molecular Vision* [electronic resource] **7**, 6-13, 2001) provides an example of a hammerhead ribozyme that is not useful for gene therapy in humans.

- Hwu, P (*Journal of immunology* (Baltimore, Md. : 1950) **150** (9) 4104-15, 1993) discloses that tumor infiltrating lymphocytes could be genetically modified to express tumor necrosis factor, but therapeutically effective levels of the protein could not be produced in vivo.

- Grove, Joanna E (*American journal of respiratory cell and molecular biology*, 27 (6) 645-51, 2002) suggests that gene therapy application to pulmonary airsaws and avleolar spaces offers potential for the future, but that safe and effective long- term gene expression using viral and non viral vectors has not been achieved.

- Sharma, S (*Gene Therapy* **4** (12) 1361-70, 1997) discloses that IL-7 and HSVtk gene-modified tumor cells were not effective in treating established parental tumors.

In addition, the specification provides no guidance as to treatment of even one disease, and provides no "working examples" which demonstrate treatment of the same. Given the "unpredictability" in the art, it is evident that "undue experimentation" would be required to practice the claimed invention. It is suggested that the term "gene therapy" be removed from the claims.

✧

Claims 29 and 32 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 29, line 1, the term "polynucleotedes" is misspelled.

- Claim 29 is indefinite as to the host. For example, if the compound is "administered" to a test tube, will a person stricken with cancer benefit from that?

- Claim 32 recites a process for preparing a compound according to formula I. This process calls for "adding amino acids or peptides" to the starting material that is named in the last three lines of the claim. However, the compound recited in the last three lines of the claim is just one compound, whereas the claim asserts that one can prepare any of the compounds that fall within the scope of formula I. For example, the starting material requires that R^1 and R^2 both be dodecane. At the same time, the claim asserts that R^1 and R^2 can be the same or different, and can contain any number of carbons within the range of 10-20. Suppose, for example, that one wanted to prepare a compound in which R^1 contains 10 carbons, and R^2 contains 20 carbons. How would one proceed, starting with the compound in which R^1 and R^2 both contain 12 carbon atoms?

✧

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DL Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1600